

Appl. No. 10/036,308  
Amendment dated October 7, 2003  
Reply to Office Action of April 7, 2003

### **REMARKS**

Applicants have received and reviewed an Office Action dated April 7, 2003. By way of response, Applicants have amended claims 4, 5, 6, 9, 10, and 13. No new matter is presented. Claims 4-6 and 9-13 are pending. Applicants submit that the pending claims are supported by the specification.

For the reasons given below, Applicants submit that the amended and newly presented claims are in condition for allowance and notification to that effect is earnestly solicited.

### **Petition for Extension of Time**

It is noted that a three-month petition for extension of time is necessary to provide for the timeliness of the response. A request for such an extension is made extending the time for response from July 7, 2003 to October 7, 2003.

### **Claim Objections**

Claims 1, 2, 4, 5, and 6 are objected to because of the interchangeable use of the terms "Alzheimer's disease" and "Alzheimer's Disease". The claims have been amended to recite "Alzheimer's disease".

### **Rejection of Claims Under 35 U.S.C. § 112, Second Paragraph**

The Examiner rejected claims 1-13 under 35 U.S.C. § 112, first paragraph. The Examiner asserted that the specification did not enable the full scope of every claim. Applicants respectfully traverse this rejection.

The Examiner asserts that the specification enables a method for diagnosing Alzheimer's disease in a subject comprising detecting specific levels of hK6 in a sample of whole blood or cerebrospinal fluid but not a method employing any sample derived from a subject. Applicants respectfully disagree. Nonetheless, to expedite allowance of this application, and not to acquiesce to this rejection, Applicants without prejudice have amended the claims to recite diagnostic methods for detecting levels of hK6 in a sample of blood or cerebrospinal fluid, and to recite that the quantitated levels are compared to levels for healthy control subjects.

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Accordingly, it is believed that the amended claims fully comply with § 112, second paragraph, and withdrawal of this rejection is respectfully requested.

**Rejection of Claims Under 35 U.S.C. § 112, second paragraph**

The Examiner rejected claims 1-13 under 35 U.S.C. § 112, second paragraph. The Examiner objected to certain terms and phrases employed in the claims. Applicants respectfully traverse this rejection.

Claims 1-3 and 7-8 have been canceled, which renders this rejection moot for these claims.

Claims 4-6 and 10-13 have been amended. In particular, claims 5-6 have been amended to add a step for diagnosing Alzheimer's disease and to recite a quantification step. Claim 4 has been amended to recite that the amount of hK6 is compared to an amount obtained for healthy control subjects. Claim 13 has been amended to recite that hK6 is detected.

Claims 4, 5, and 6 and claims dependent therefrom recite that a statistically significant increase in hK6 levels compared with levels for the healthy control subjects is indicative of Alzheimer's disease. Methods for calculating statistically significant increases in hK6 levels are disclosed in the application and are well known in the art (e.g. t-test or Mann-Whitney test).

Accordingly, it is believed that the amended claims fully comply with § 112, second paragraph, and withdrawal of this rejection is respectfully requested.

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Summary

In summary, Applicants submit that each of claims 4-6 and 9-13 are in condition for allowance. The Examiner is invited to contact Applicant's undersigned representative at the telephone number listed below, if the Examiner believes that doing so will expedite prosecution of this application.

Respectfully submitted,

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Dated: Oct 7, 2003

By: Mark T. Skoog  
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